

NOT FOR PUBLICATION

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

TYCO HEALTHCARE GROUP LP and
MALLINCKRODT INC.,

Plaintiffs,

v.

MUTUAL PHARMACEUTICAL COMPANY,
INC. and UNITED RESEARCH
LABORATORIES, INC.,

Defendants.

Civil Action No. 07-1299 (SRC)

OPINION

CHESLER, U.S.D.J.

This matter comes before the Court on the applications by Plaintiffs Tyco Healthcare Group LP (“Tyco”) and Mallinckrodt Inc. (“Mallinckrodt”) and Defendants Mutual Pharmaceutical Company, Inc. and United Research Laboratories, Inc. (collectively, “Mutual”) for claim construction to resolve disputes over the construction of claim terms in U.S. Patent No. 5,211,954 (the “’954 patent”). This Court has examined the disputes over construction of these claim terms and, for the reasons stated below, resolves these disputes by rejecting the constructions proposed by Plaintiffs.

BACKGROUND

This case arises out of an action for patent infringement. Briefly, Mallinckrodt owns U.S. Patent No. 5,211,954, which is directed to a low-dose temazepam composition. Tyco holds an FDA-approved supplement to new drug application No. 18-163 for Restoril® temazepam

capsules. Mutual filed an ANDA, seeking approval from the FDA to engage in the manufacture and sale of certain temazepam products. On March 20, 2007, Plaintiffs responded with this infringement action. Plaintiffs originally asserted infringement of four patents, but three of those patents have since expired, leaving only the '954 patent at issue.

ANALYSIS

I. The law of claim construction

A court's determination "of patent infringement requires a two-step process: first, the court determines the meaning of the disputed claim terms, then the accused device is compared to the claims as construed to determine infringement." Acumed LLC v. Stryker Corp., 483 F.3d 800, 804 (Fed. Cir. 2007). The Court decides claim construction as a matter of law: "the construction of a patent, including terms of art within its claim, is exclusively within the province of the court." Markman v. Westview Instruments, 517 U.S. 370, 372 (1996).

The focus of claim construction is the claim language itself:

It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude. Attending this principle, a claim construction analysis must begin and remain centered on the claim language itself, for that is the language the patentee has chosen to 'particularly point[] out and distinctly claim[] the subject matter which the patentee regards as his invention.'

Innova/Pure Water, Inc. v. Safari Water Filtration Sys., 381 F.3d 1111, 1115-1116 (Fed. Cir. 2004) (citations omitted).

The Federal Circuit has established this framework for the construction of claim language:

We have frequently stated that the words of a claim 'are generally given their ordinary and customary meaning.' We have made clear, moreover, that the

ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application. The inquiry into how a person of ordinary skill in the art understands a claim term provides an objective baseline from which to begin claim interpretation. . .

In some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words. In such circumstances, general purpose dictionaries may be helpful. In many cases that give rise to litigation, however, determining the ordinary and customary meaning of the claim requires examination of terms that have a particular meaning in a field of art. Because the meaning of a claim term as understood by persons of skill in the art is often not immediately apparent, and because patentees frequently use terms idiosyncratically, the court looks to those sources available to the public that show what a person of skill in the art would have understood disputed claim language to mean. Those sources include the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art.

Phillips v. AWH Corp., 415 F.3d 1303, 1312-1314 (Fed. Cir. 2005) (citations omitted).

II. Claim construction of the disputed terms

The '954 patent has just two claims, and the claims have identical language except for the dosage of temazepam:

1. A hard gelatin capsule containing a temazepam formulation consisting essentially of 6 to 8 milligrams of crystalline temazepam having a surface area of from 0.65 to 1.1 m.sup.2 /g and 95% of the temazepam having a particle size of less than 65 microns in admixture with a pharmaceutically acceptable carrier therefor.
2. A hard gelatin capsule containing a temazepam formulation consisting essentially of 7.5 milligrams of crystalline temazepam having a surface area of from 0.65 to 1.1 m.sup.2 /g and 95% of the temazepam having a particle size of less than 65 microns in admixture with a pharmaceutically acceptable carrier therefor.

The parties initially briefed a set of claim construction issues, but were then able to

resolve some of the disputes. The parties have narrowed their claim construction disputes to three issues: 1) does the phrase “consisting essentially of” operate to broaden the scope of the surface area range? 2) is “surface area” limited to one measurement method? and 3) does the “surface area” range apply to less than the entire dosage amount?

A. Does the phrase “consisting essentially of” operate to broaden the scope of the surface area range?

Both claims limit the invention to “a temazepam formulation consisting essentially of [amount of] crystalline temazepam having a surface area of from 0.65 to 1.1 m.^{sup.2} /g . . .” Plaintiffs contend that the phrase “consisting essentially of” operates to broaden the scope of the surface area range beyond the limits specified, such that the claim scope includes “crystalline temazepam having other specific surface area values that do not materially affect the basic and novel characteristics of the claimed invention.” (Pls.’ Supp. Br. 2.) Defendants disagree.

Plaintiffs’ only argument in support of their position rests on their assertion that the Federal Circuit has a standard approach to the interpretation of the phrase “consisting essentially of:”

“Consisting essentially of” is a transition phrase commonly used to signal a partially open claim in a patent. Typically, “consisting essentially of” precedes a list of ingredients in a composition claim or a series of steps in a process claim. By using the term “consisting essentially of,” the drafter signals that the invention necessarily includes the listed ingredients and is open to unlisted ingredients that do not materially affect the basic and novel properties of the invention. A “consisting essentially of” claim occupies a middle ground between closed claims that are written in a “consisting of” format and fully open claims that are drafted in a “comprising” format.

PPG Indus. v. Guardian Indus. Corp., 156 F.3d 1351, 1354 (Fed. Cir. 1998). This Court need not reach the question of the extent to which this operates as a *per se* rule of construction, as the

principles of PPG do not support Plaintiffs' argument. Under PPG, the invention is open to certain *unlisted* ingredients. Id. Temazepam is a listed ingredient in the claims of the '954 patent, not an unlisted ingredient. As such, Plaintiffs' argument, that "consisting essentially of" can operate to leave the claim open to additional amounts of temazepam, fails from the start.

This is reason enough to reject Plaintiffs' position, but there are additional reasons to do so. Plaintiffs ask this Court to take claim language that appears to be meaningfully precise and read the precision out of it. Paragraph 2 of 35 U.S.C. § 112 states: "The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." Plaintiffs' position runs contrary to this statutory requirement. This Court cannot take claim language that distinctly claims the subject matter of the invention and, through claim construction, diffuse the particularity or blur the distinctness of that language. See Texas Instruments v. United States ITC, 988 F.2d 1165, 1171 (Fed. Cir. 1993) (rejecting a claim construction that "would read an express limitation out of the claims.") Plaintiffs point to no law that shows otherwise.

In the briefs, neither party confronts the issue of the definiteness requirement in paragraph 2 of 35 U.S.C. § 112. See Halliburton Energy Servs. v. M-I LLC, 514 F.3d 1244, 1249 (Fed. Cir. 2008). Definiteness requires that a person of ordinary skill in the art be able to ascertain a "meaningfully precise claim scope." Id. at 1251. In the most recent major case on claim construction, Phillips, the Federal Circuit expressly characterized as "bedrock" the principle that the claims define – and must precisely define – the boundaries of the invention. 415 F.3d at 1313. In that discussion in Phillips, the Federal Circuit cited the long history, beginning in at least 1836, of this principle in patent law. In the list of citations, the Court cited the well-known

words of the Supreme Court in McCarty v. Lehigh Valley R.R. Co., 160 U.S. 110, 116 (1895):

[W]e know of no principle of law which would authorize us to read into a claim an element which is not present, for the purpose of making out a case of novelty or infringement. The difficulty is that if we once begin to include elements not mentioned in the claim in order to limit such claim and avoid a defence of anticipation, we should never know where to stop.

This is exactly the problem with agreeing with Plaintiffs' argument: if, before determining infringement, courts read the precision out of the claim language, they will never know where to stop. Plaintiffs ask the Court to proceed down this path. If this Court were to agree with Plaintiffs' position, it would replace clarity with ambiguity, defeating the purpose of claim construction.

The claims state a clear, specific range for the surface area of crystalline temazepam and are construed precisely as written. "Consisting essentially of" does not operate to broaden the scope of the surface area range beyond the exact limits specified.

B. Is "surface area" limited to the measurement method of Example 1?

The second claim construction dispute concerns whether "surface area" must be measured using the specific equipment and procedure stated in Example 1 of the specification. Plaintiffs argue that, although the claims do not speak to how surface area is measured, this Court should construe them as including a limitation to the measurement method described in Example 1. Plaintiffs briefly argue that one of ordinary skill in art would have understood the claim term "surface area" to be measured using the equipment and procedure stated in Example 1 of the specification.

Plaintiffs cite no law in support of this position, which appears contrary to established Federal Circuit principles of claim construction. The Federal Circuit has detailed the legal

requirements for the use of the specification as well as extrinsic evidence in claim construction.

As to the role of the specification in claim construction, the basic principle holds that the language of the claims is read in the context of the specification:

[O]ur cases recognize that the specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor's lexicography governs. In other cases, the specification may reveal an intentional disclaimer, or disavowal, of claim scope by the inventor. In that instance as well, the inventor has dictated the correct claim scope, and the inventor's intention, as expressed in the specification, is regarded as dispositive.

Phillips, 415 F.3d at 1316 (citation omitted). Thus, Phillips sets forth the two main approaches to use of the specification in claim construction: 1) to reveal special meanings of words (the inventor's lexicography); or 2) to reveal intentional disclaimers of claim scope. Plaintiffs' briefs do not articulate any argument involving either approach. Plaintiffs do not contend that the inventor assigned any special meaning to "surface area," such that it could only be measured using the method of Example 1, nor do they contend that the specification reveals an intentional disclaimer of claim scope along such lines.

Many cases expressly warn against limiting claim scope to the embodiments described in the specification. Thus, in Phillips, the Court wrote: "although the specification often describes very specific embodiments of the invention, we have repeatedly warned against confining the claims to those embodiments." Phillips, 415 F.3d at 1323. Another important case giving such a warning is Liebel-Flarsheim: "Even when the specification describes only a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using 'words or expressions of manifest exclusion or restriction.'" Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 906 (Fed. Cir. 2004) (quoting

Teleflex, Inc. v. Ficosa N. Am. Corp., 299 F.3d 1313, 1327 (Fed. Cir. 2002)).

Plaintiffs do not argue, nor does this Court observe, that the patentee demonstrated a clear intention to limit the claims to temazepam with a surface area measured by the equipment and procedure stated in Example 1 of the specification. Plaintiffs do not argue that the language of Example 1 constitutes an expression of manifest exclusion or restriction. Moreover, Plaintiffs do not assert that the method of measurement of surface area was material to what was invented. Not to belabor the obvious, but Example 1 is one example of two. Example 1 appears to be an example provided by the inventor to help teach how to make and use the invention, as explained by the Federal Circuit:

To avoid importing limitations from the specification into the claims, it is important to keep in mind that the purposes of the specification are to teach and enable those of skill in the art to make and use the invention and to provide a best mode for doing so. One of the best ways to teach a person of ordinary skill in the art how to make and use the invention is to provide an example of how to practice the invention in a particular case. Much of the time, upon reading the specification in that context, it will become clear whether the patentee is setting out specific examples of the invention to accomplish those goals, or whether the patentee instead intends for the claims and the embodiments in the specification to be strictly coextensive.

Phillips, 415 F.3d at 1323 (citations omitted). In this patent, the reference to the measurement equipment and procedure stated in Example 1 of the specification appears to be exemplary in nature.

Plaintiffs also offer the opinion of their expert, Dr. Luk, that one of ordinary skill in the art would have understood that “surface area” refers to values determined by the measurement equipment and procedure stated in Example 1. (Luk Decl. ¶ 27.) Luk’s declaration is extrinsic evidence of the meaning of claim terms. In Phillips, the Federal Circuit discussed the role of

extrinsic evidence in claim construction and stated this conclusion:

In sum, extrinsic evidence may be useful to the court, but it is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence. Nonetheless, because extrinsic evidence can help educate the court regarding the field of the invention and can help the court determine what a person of ordinary skill in the art would understand claim terms to mean, it is permissible for the district court in its sound discretion to admit and use such evidence.

Phillips, 415 F.3d at 1319.

Luk states that, at the time the patent was drafted, both the surface area measurement method in Example 1 (the dynamic method) as well as a static method were known in the art. (Luk. Decl. ¶¶ 16-18.) Given that, Plaintiffs fail to explain why one of ordinary skill in the art would have necessarily understood surface area to be measured by one method to the exclusion of the other. Furthermore, while Luk states that Example 1 describes the dynamic method, Example 2 does not describe a surface area measurement method.

The intrinsic evidence is insufficient to justify finding a claim limitation in Example 1. Nor does this Court find the extrinsic evidence of Luk's expert testimony to be sufficiently reliable and useful in claim construction to rely on it. There simply is insufficient basis to conclude that the inventor intended to limit the invention to products having a surface area measured in a particular way.

Plaintiffs have thus provided no legal basis to justify importing a limitation based on measurement method into the claims.

C. Does the “surface area” range apply to less than the entire dosage amount?

As stated by Defendants, the third disputed claim construction issue is “whether the ‘surface area’ range applies to less than the entire dosage amount of the crystalline temazepam in

the capsule.” (Defs.’ Supp. Br. 2.) Plaintiffs contend that the claims “are open to the presence of amounts of crystalline temazepam having a specific surface area outside of the recited range.”

(Pls.’ Supp. Br. 4.) In support of this position, Plaintiffs again rely entirely on the “consisting essentially of” argument already considered and rejected by this Court. Temazepam is not an unlisted ingredient, and the claims are not open to additional amounts of temazepam.

Conspicuously absent from Plaintiffs’ briefs is a citation to any case in which a court found that “consisting essentially of” opened the claim to additional amounts of a listed ingredient.

CONCLUSION

This Court has examined the three disputes over claim construction raised by the parties and, for the reasons stated above, resolves these disputes by rejecting the interpretations proposed by Plaintiffs. Specifically, the disputes are resolved as follows: 1) The surface area range stated in the claims is read precisely as written. The phrase “consisting essentially of” does not broaden the scope of the surface area range. 2) The phrase “surface area” is not limited to the measurement method stated in Example 1. 3) The specific range of “surface area” does not apply to less than the entire dosage amount.

s/ Stanley R. Chesler
Stanley R. Chesler, U.S.D.J.

Dated: January 5, 2009